

Notice of Allowability

Application No.

09/810,020

Examiner

Dr. Kailash C. Srivastava

Applicant(s)

DOWNS, ROBERT CHARLES

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 11/07/2003.
2. ☒ The allowed claim(s) is/are 59-79.
3. ☒ The drawings filed on 16 March 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 11/07/2003, 01/07/2003 and 3/16/2004
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

Examiner's Amendment/Comments

1. Pursuant to the telephonic interview Of October 2 and 8, 2003 with Applicant's representative:
 - i the Restriction Requirement set forth in Office Action mailed 19 March 2003 is reverted to the restriction requirement mailed September 18, 2002;
 - ii. the Office Action mailed 01 July 2003 is hereby vacated.

CLAIMS STATUS

2. Claims 32-58 are canceled.
3. Claims 1-31 are pending.

Restriction/Election

4. Applicant's election without traverse of Group I, Claims 1-31 and following Species Indicia filed December 24, 2002 in response to Office Action mailed September 18, 2002 is acknowledged and entered.

- | | |
|----------------|--|
| A.a. | Centrifugation; |
| B.bb. | Isolating recombinant proteins; |
| B.bb.bba. | Crystallizing the isolated sample; |
| B.bb.bba.bbba. | Analyzing by X-ray crystallography; |
| C.ii | Attaching a robotic gripper apparatus; |
| D.x. | Prokaryotic cells; |
| D.x..xb. | Gene variant in a vector; and |
| E.2. | Anaerobic fermentation. |

In accordance with the literature search for prior art, claims 21-22, and 27, previously

restricted as species and therefore not considered as a result of a restriction requirement are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Since the election is made without traverse, the restriction requirement is deemed proper and is made FINAL.

Accordingly, Claims 3, 6, 8-11, 13 and 29-31 are withdrawn from further consideration as being directed to a non-elected invention. See 37 CFR §1.142(b) and MPEP § 821.03.

5. Claims 1-2, 4-5, 7, 12 and 14-28 are examined on merits.

Information Disclosure Statement

6. Applicant's Information Disclosures filed 16 March 2001, 07 January, and 07 November 2003 have been made of record and considered.

Examiner's Amendment

7. An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicants, an amendment may be filed as provided by 37 CFR §1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this Examiner's amendment was given in a telephone interview with Mr. Christopher C. Sappenfield on 26 October 2004.

In the Claims:

- Claims 1-31 have been cancelled.
- Claims 59-79 have been added as follows:

--59. A method comprising:
performing a plurality of fermentations, each fermentation in a different sample vessel; and
performing a further processing step on the plurality of fermented samples where the sample
is retained in the same sample vessel as the fermentation during the processing step.

60. The method of claim 59, wherein the further processing step is centrifugation of
the fermented samples in the sample vessels in which the fermentations were performed.

61. The method of claim 59, further comprising grasping the sample vessels with a
robotic gripper apparatus in order to move the sample vessels from a first location where the
fermentations are performed to a second location where the further processing step is
performed.

62. The method of claim 59, wherein the fermentations comprise fermentations of
prokaryotic or eukaryotic cells, or viral particles.

63. The method of claim 59, wherein the fermentation is an anaerobic fermentation.

64. The method of claim 59, wherein the fermentation is a bacterial fermentation
where a recombinant protein is expressed.

65. The method of claim 64, wherein the method further comprises isolating
recombinant proteins expressed during the fermentations after the further processing step.

66. The method of claim 65, wherein the recombinant proteins are isolated by column
chromatography.

67. The method of claim 65, wherein the method further comprises crystallizing the isolated recombinant proteins.

68. The method of claim 67, wherein the method includes crystallizing tens to thousands of proteins per day.

69. The method of claim 67, wherein the crystallized proteins are used to design drugs.

70. The method of claim 67, wherein structures of the crystallized proteins are analyzed by X-ray crystallography.

71. The method of claim 70, wherein the protein structures are used in computer assisted drug design.

72. The method of claim 59, wherein the further processing step uses a robot that tests tens to thousands of variants of a protein.

73. The method of claim 72, wherein the robot includes a plate handler that carries plates from one station to another.

74. The method of claim 59, wherein the samples comprise a prokaryotic, eukaryotic, or viral expression system comprising a gene fragment or variant in a vector.

75. The method of claim 59, wherein performing a plurality of fermentations includes performing at least 96 fermentations at the same time.

76. The method of claim 59, wherein hundreds of fermentations are performed per day using the method.

77. The method of claim 68, further comprising analyzing on an imaging station, more than one million images from thousands of crystallizations.

78. The method of claim 68, further comprising identifying crystals from the crystallizations, using crystal-detecting algorithms.

79. The method of claim 68, further comprising using a robot to mount and center about 30 to about 50 crystals per hour with the robot. --

8. The following is Examiner's statement of reasons for allowance:

The closest prior art are: Roberts (U. S. Patent 6,197,517) and Rudenko et al. (WO97/15588). Roberts teaches multiple fermentations to obtain a recombinant protein through culturing a microbial cell in which said recombinant protein is expressed. Subsequently, the proteins are purified with art-known techniques (Column 27, Lines 26-32). Roberts, however, does not explicitly teach isolation and purification of said recombinant protein. Rudenko et al. teach expression of a recombinant protein in either prokaryotic (e.g., bacteria) or eukaryotic (i.e., yeasts, fungi etc.) cells (abstract, Lines 2-10, Page 11, Lines 20-41) as well as isolation, purification and further characterization of a recombinant protein (Page 13, Lines 11-42). Rudenko et al. also teach that with their method of protein isolation and purification, 1-100 mg/ml of purified protein is obtained (Page 13, Lines 11-42). Note that the techniques and methods that Roberts and Rudenko et al. teach are applicable to a single or to a plurality of samples.

Neither Roberts, nor Rudenko, however, teach performing a plurality of fermentations, each fermentation in a different sample vessel, performing a further processing step on the

plurality of fermented samples where the sample is retained in the same sample vessel as the fermentation during the processing step, whereas the further processing step is centrifugation of the fermented samples in the sample vessels in which the fermentations were performed. Thus, none of the prior art cited *supra* alone or in combination teach or reasonably suggest the method claimed in instant invention.

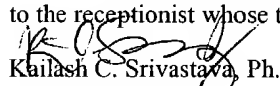
Any comments considered necessary by applicants must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Claims 59-79 are allowed.

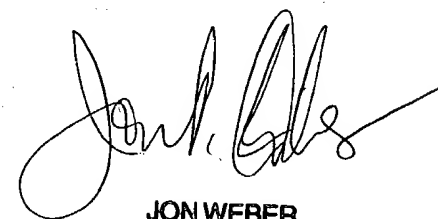
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (571) 272-0926 Monday through Thursday. The fax phone number for the organization where this application or proceeding is assigned is (703)-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Kailash C. Srivastava, Ph.D.
Patent Examiner
Art Unit 1651
(571) 272-0923

November 8, 2004


JON WEBER
SUPERVISORY PATENT EXAMINER